

WHAT IS CLAIMED IS:

1. A stable composition for a benzimidazole derivative, the composition comprising:
 - (a) a substrate, said substrate featuring the benzimidazole derivative; and
 - (b) an enteric coating material layered directly over said substrate, said enteric coating material having a pH value of at least about 6.5, thereby obviating the need for an intermediate layer between said substrate and said enteric coating, with the proviso that said enteric coating material does not include HPMCP (hydroxypropyl methylcellulose phthalate).
2. The composition of claim 1, wherein said substrate is an active core for containing the benzimidazole derivative.
3. The composition of claim 2, wherein said active core is selected from the group consisting of a pellet, a bead and a tablet.
4. The composition of claim 2, wherein said active core is a tablet formed by compression.
5. The composition of claim 1, wherein said substrate features:
 - (i) a neutral core; and
 - (ii) an active coating containing the benzimidazole derivative, said active coating being layered over said neutral core; such that the composition is in a form of a pellet
6. The composition of claim 1, wherein said substrate features a core containing the benzimidazole derivative with a suitable binding agent, said core being prepared by spheronisation and pelletization; such that the composition is in a form of a pellet.
7. The composition of claim 1, wherein said enteric coating material includes at least one enteric material selected from the group consisting of hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate, cellulose acetate phthalate, cellulose acetate trimellitate,

hydroxypropyl methylcellulose phthalate, polymethacrylic acid methyl methacrylate and polymethacrylic acid ethyl methacrylate.

8. The composition of claim 7, wherein said enteric coating material further comprises an alkaline compound, such that said pH value is adjusted by adding said alkaline compound to said enteric material.

9. The composition of claim 8, wherein said alkaline compound is an inorganic alkaline compound.

10. The composition of claim 9, wherein said alkaline compound is selected from the group consisting of basic sodium, potassium and ammonium hydroxide.

11. The composition of claim 10, wherein said enteric coating material is at least about 60 % neutralized by adding said alkaline compound.

12. The composition of claim 11, wherein said enteric coating material is at least about 80 % neutralized by adding said alkaline compound.

13. The composition of claim 11, wherein said enteric coating material is at least about 95 % neutralized by adding said alkaline compound.

14. The composition of claim 8, wherein said pH value is in a range of from about 7 to about 10.

15. The composition of claim 8, wherein said enteric coating material further comprises a plasticizer.

16. The composition of claim 15, wherein said plasticizer is selected from the group consisting of a citric acid ester and a phthalic acid ester.

17. The composition of claim 1, wherein the benzimidazole derivative is selected from the group consisting of Omeprazole, Pantoprazole, Lansoprazole, Leminoprazole, Perprazole, Rabeprazole, and pharmaceutically acceptable salts thereof.

18. ✓ A stable composition for a benzimidazole derivative, the composition consisting essentially of:

- (a) a substrate, said substrate featuring the benzimidazole derivative; and
- (b) an enteric coating material layered over said substrate, said enteric coating material having a pH value of at least about 6.5 by an alkaline compound, such that said pH value is adjusted by adding said alkaline compound to said enteric material.

19. The composition of claim 18, wherein said substrate is an active core for containing the benzimidazole derivative.

20. The composition of claim 19, wherein said active core is selected from the group consisting of a pellet, a bead and a tablet, said active core being formed by embedding the benzimidazole derivative in poloxamer.

21. The composition of claim 19, wherein said active core is a tablet formed by compression.

22. The composition of claim 18, wherein said substrate features:

- (i) a neutral core; and
- (ii) an active coating containing the benzimidazole derivative, said active coating being layered over said neutral core.

23. The composition of claim 18, wherein said enteric coating material includes at least one enteric material selected from the group consisting of hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, polymethacrylic acid methyl methacrylate and polymethacrylic acid ethyl methacrylate.

24. The composition of claim 23, wherein said alkaline compound is an inorganic alkaline salt compound.

25. The composition of claim 24, wherein said alkaline compound is selected from the group consisting of basic sodium, potassium or ammonium hydroxide.

26. The composition of claim 25, wherein said enteric coating material is at least about 60 % neutralized by adding said alkaline compound.

27. The composition of claim 26, wherein said enteric coating material is at least about 80 % neutralized by adding said alkaline compound.

28. The composition of claim 27, wherein said enteric coating material is at least about 95 % neutralized by adding said alkaline compound.

29. The composition of claim 24, wherein said pH value is in a range of from about 7 to about 10.

30. The composition of claim 24, wherein said enteric coating material further comprises a plasticizer.

31. The composition of claim 30, wherein said plasticizer is selected from the group consisting of a citric acid ester and a phthalic acid ester.

32. The composition of claim 18, wherein the benzimidazole derivative is selected from the group consisting of Omeprazole, Pantoprazole, Lansoprazole, Leminoprazole, Perprazole, Rabeprazole, and pharmaceutically acceptable salts thereof.

33. A method for producing a stable composition for a benzimidazole derivative, the method comprising the steps of:

- (a) forming a substrate with the benzimidazole derivative;
- (b) preparing an enteric coating material having a pH value of at least about 6.5; and

(c) layering said enteric coating material directly over said substrate, with the proviso that said enteric coating material does not include HPMCP (hydroxypropyl methylcellulose phthalate).

34. The method of claim 33, wherein said substrate is formed by melting poloxamer and by mixing the benzimidazole derivative into said poloxamer.

35. The method of claim 33, wherein said substrate is formed by direct compression.

36. The method of claim 33, wherein said substrate is formed by wet granulation.

37. The method of claim 33, wherein said substrate is formed by coating on an inert core.

38. The method of claim 33, wherein said enteric coating material is prepared by the steps of:

- (i) mixing an enteric material with water to form a mixture; and
- (ii) adding an alkaline compound to said mixture to form an aqueous solution having a pH value of from about 7 to about 10.

39. The method of claim 33, wherein said enteric coating material is prepared by the steps of:

- (i) mixing an enteric material with water and alcohol to form a mixture; and
- (ii) adding an alkaline compound to said mixture to form an aqueous solution having a pH value of from about 7 to about 10.